

# Considerations with regard to TPSAC's review of dissolvable tobacco products

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## Overview

The Family Smoking Prevention and Tobacco Control Act (the Act) charges the Tobacco Products Scientific Advisory Committee (TPSAC) with developing a report on dissolvable tobacco products. The specific charge is:

“(f) DISSOLVABLE TOBACCO PRODUCTS.—

“(1) REFERRAL; CONSIDERATIONS.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 917(c)(4), the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).

“(2) REPORT AND RECOMMENDATION.—Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

“(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act at any time applicable to any dissolvable tobacco product.

This charge is parallel to that given TPSAC with regard to the use of menthol in cigarettes, although for dissolvable tobacco products TPSAC is requested to evaluate the “...nature and impact” of these products on the public health and not simply “impact” as specified for menthol in cigarettes. Additionally, TPSAC is asked to examine impact in children specifically, but not in other particular groups. Of course, there are substantial differences in the scope of evidence available to TPSAC for menthol in cigarettes, which had been on the market for decades and relatively extensively studied, compared with dissolvable products, only now entering the market.

In addressing the impact of menthol cigarettes on public health, TPSAC proposed that an adverse effect on public health from menthol in cigarettes could come as a result of an increased number of smokers, compared to the counterfactual of having only cigarettes without menthol as an additive, and as a result of increased risk for developing disease in smokers of menthol compared with nonmenthol cigarettes. A conceptual framework was proposed and used as the basis for a systematic review of the literature, evidence gathering, and development of a model. The planning document for the menthol report is attached for reference.

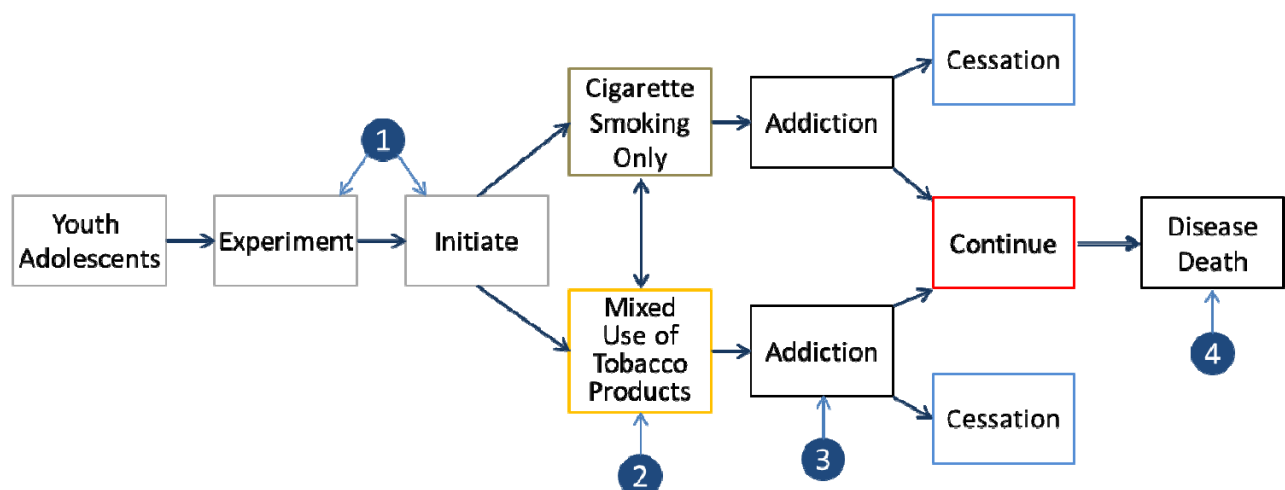
While the evidence base for dissolvable tobacco products is quite sparse, the general approach followed by TPSAC in the instance of menthol cigarettes remains useful. Its conceptualization of public health impact within a specified framework, the systematic approach to evidence synthesis, and the classification of strength of evidence are equally applicable to dissolvable tobacco products.

### Approach

As a starting point, TPSAC proposes a conceptual framework that is parallel to that developed for menthol cigarettes (Figure 1). The framework offers hypothesized mechanisms by which dissolvable tobacco products could have impact on public health. The pathways include 1) increased experimentation and initiation of cigarette smoking as a consequence of access to an oral, nicotine-containing product; 2) experimental use leading to an established pattern of mixed use of tobacco products (e.g., dissolvable products, other smokeless products, and/or cigarettes); 3) decreased likelihood of smoking cessation, given a nicotine-delivering product that can be used where smoking is not permitted; and 4) differing profile of risk for tobacco-caused diseases and mortality. Through the first three mechanisms, the pool of nicotine addicted persons in the population would be increased. With use of dissolvable products, risks for tobacco-caused diseases and death might be altered from the risks associated with a profile of smoking cigarettes only.

As with menthol cigarettes, the model indicates the key items of evidence that the committee will need in meeting its charge. Direct epidemiological evidence is lacking and consequently the committee will need to address its charge through gaining understanding of the delivery of nicotine by the dissolvable products and their potential to facilitate initiation of smoking or to maintain addiction, thereby reducing cessation. A judgment will also be needed on the fourth mechanism, the impact of availability of dissolvables on risks for tobacco-caused diseases and death.

Figure 1. Conceptual Framework: From Experimentation to Disease



## CONSIDERATIONS WITH REGARD TO THE MENTHOL REPORT

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### **Overview**

In writing a report on menthol and offering a recommendation as to whether it should be banned, the Tobacco Products Scientific Advisory Committee (TPSAC) will use an evidence-based framework. In advance of writing its report, the TPSAC has been provided with information in the form of written submissions and meeting presentations. This information has come from literature review by FDA staff and from the tobacco companies, in response to questions from TPSAC.

As TPSAC evaluates this information, it will do so within an overall model of cigarette smoking that defines points at which the availability of menthol in cigarettes could harm either the health of the individual smokers or of the public generally (Figure 1). TPSAC has the mandate of assessing harm to both smokers and the population, and will use this framework for its overall judgment and recommendation.

The model begins with experimentation with cigarette smoking on the part of children, adolescents, and young adults and ends with the development of disease and death caused by smoking cigarettes. The model is not inclusive in showing all factors that contribute to this sequence from experimentation to disease incidence, but it does include those that might be affected by menthol cigarettes.

### **Questions Related To Menthol**

The following questions will be addressed and answered according to a standardized terminology for strength of evidence. Each is relevant to the determination as to whether menthol should be banned from inclusion in cigarettes.

#### **Related to Individual Smokers**

1. Does access to menthol cigarettes increase the likelihood of experimentation?
2. Does access to menthol cigarettes increase the likelihood of becoming a regular smoker?
3. Does inclusion of menthol in cigarette increase the likelihood of the smoker becoming addicted?
4. Does inclusion of menthol in cigarettes increase the degree of addiction of the smoker?
5. Are smokers of menthol cigarettes less likely to quit successfully than smokers of non-menthol cigarettes?
6. Do biomarker studies indicate that smokers of menthol cigarettes receive greater doses of harmful agents per cigarette smoked, in comparison with smokers of non-menthol cigarettes?
7. Do smokers of menthol cigarettes have increased risk for diseases caused by smoking in comparison with smokers of non-menthol cigarettes?

## Smoking at the Population Level

1. Does the availability of menthol cigarettes increase the prevalence of smoking in the population, beyond the anticipated prevalence if such cigarettes were not available? In subgroups within the population?
2. Does tobacco company marketing of menthol cigarettes increase the prevalence of smoking beyond the anticipated prevalence if such cigarettes were not available? In subgroups within the population?

(Note that the committee will need to discuss the handling of the higher prevalence of menthol within particular population groups; as well as the marketing of menthol cigarettes towards these subgroups. Marketing *per se* does not represent an adverse consequence of menthol cigarettes. As presented by the tobacco companies, they market to menthol smokers.)

## Evidence Evaluation

TPSAC will review the most relevant evidence within the time frame for the development of its report on menthol. It will reach conclusions on the questions above, framing its conclusions in the foundation of evidence reviewed and summarized in its report. Key principles for its synthesis and evaluation will include a transparent process, standardized language for its conclusions, and identification of key uncertainties and their implications for reaching conclusions. The judgments provided will reflect committee consensus to the extent possible.

In providing answers to the questions above ( or to those addressed in subsequent reports), the committee will consider:

- . The extent of the evidence available;
- . The strengths and limitations of the evidence;
- . Key gaps and uncertainties in the evidence;
- . The generalizability of study findings.

Figure 1. Menthol: From Experimentation to Disease Risk

